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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,282	12/19/2001	Mark W. Bleyer	3433-333	5918

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Woodard, Emhardt, Naughton, Moriarty and McNett
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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT	PAPER NUMBER
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1633

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12/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/025,282	Applicant(s) BLEYER ET AL.	
	Examiner Maria Leavitt	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-60 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-60 and 62-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 19, 2007 has been entered. Species restriction remains correct and active for the request for continued examination of the instant Application.
2. Status of claims. Claims 36-60 and 62-65 are pending. Claim 54 has been amended by Applicants' amendment filed on 09-19-2007. Therefore, claims 36-60 and 62-65 are currently under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Remaining rejections in response to Applicant arguments or amendments

35 U.S.C. 112, first paragraph, written description

Claim Rejections - 35 USC § 112

Claims 54 –60, 62 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Amended claim 54 and dependent claims 55 –60, 62 broadly embrace a genus of bonding techniques to generate a multilayer radiopaque implantable device, wherein collagenous strips are bonded using sutures, staples, biocompatible adhesives, or dehydrating overlapping strips.

Applicant provides only one example wherein a plurality of tela submucosa strips can be fused to one another, by compressing overlapping area of the strips under dehydrating conditions, to form an overall planar constructs having a surface area greater than that of any one planar surface of the individual strips used to shape the construct. Additionally, a radiopaque powder can be disposed within these strips (p.21, paragraph 2). Further, Applicant discloses that shapes of constructs can be made by using sutures, staples, and biocompatible adhesives such as collagen binding paste or dehydrating overlapping structures. However, it is noted that there is not disclosure in the specification of how any of the techniques used to shape the strips can simultaneously be used to intimately join two or more layers of collagenous strips of biological tissue. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species bonding techniques encompassed by the claims as one of skill in the art cannot envision how collagenous strips of submucosa tissue can be merely bonded by staples to generate an implantable biomaterial e.g., a prosthesis, or how the biological tissue can be intimately joined using sutures to manufacture a functional bio implantable multi layer material to promote remodeling at the site of implantation in a patient. The mere recitation in the claims of bonding techniques without full, clear, concise and exact terms in the specification for the correlation for the structure/function relationship of said bonding techniques is not deemed sufficient to reasonably convey to one skilled in the art that Applicant has possession of

the bonding techniques as claimed at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Reply to applicant arguments as they relate to rejection of Claims 54 –60, 62, under 35

U.S.C. 112, first paragraph, written description

On page 8 of Remarks, Applicants argue that “claim 54 has been amended to specify the bonding techniques identified in the application. Support for such an amendment can be found in the present application at, for example, paragraph [0069]. One skilled in the art would be able to form the claimed devices based on these bonding techniques without any undue experimentation” and as such, it is believed that the claims 54 –60, 62 overcome the written description rejection under U.S.C. 112, first paragraph. Such is not persuasive.

At the outset, the examiner strenuously disagrees with the Applicants’ position that the skilled artisan would be able to manufacture the claimed devices based on these bonding techniques without any undue experimentation. Paragraph [0069] refers to techniques that generate shapes of constructs and not bonding of two layers. Moreover, Paragraph [0069] recites that “then heating the structure as described in U.S. Patent No 3,562,820”. Patent 3,562,820 discloses at col. 2, lines 24-35, at col. 3 lines 11-20, col. 4, lines 71-73, bonding techniques comprising swelling of the exposed surfaces so as to produce an adhesive or glue like used as bonding agent to generate a multi-layered structure. Clearly, the disclosure does not provide sufficient guidance commensurate with the scope of the claims

35 U.S.C. 112, first paragraph, scope of enablement

Claims 54 –60, and 62 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 54 –60 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for:

An implantable medical device, comprising;

A multi-strip bioabsorbable collagenous based submucosa, wherein a radiopaque marker is disposed in between collagenous layer segments of said multi-strip bioabsorbable collagenous based submucosa to promote remodeling of tissue of the patient at a site at which said bioabsorbable collagenous based submucosa is implanted,

does not reasonably provide enablement for a radiopaque, implantable biomaterial device, wherein multiple collagenous strips are bonded to one another in any mode to form a functional multilayer structure to yield results contemplated by Applicant

Applicant has not provided a response that properly applies to the rejection of claims 54 –60, 62 under 35 U.S.C. 112, first paragraph, scope of enablement requirement, but has provided a single response that is equally relevant to rejections of claims under 35 U.S.C. 112, first paragraph, written description requirement, and scope of enablement. These are different rejections that merit separate responses as they pertain to different grounds of rejection. Please, note that the examiner's response to argument related to Applicant's traversal of enablement rejection appear in the paragraph below under rejection Claim Rejections - 35 USC § 112 -scope of enablement. See MPEP § [2161]

Reply to applicant arguments as they relate to rejection of Claims 54 –60, 62, under 35

U.S.C. 112, first paragraph, scope of enablement

On page 8 of Remarks, Applicants argue that “claim 54 has been amended to specify the bonding techniques identified in the application. Support for such an amendment can be found in the present application at, for example, paragraph [0069]. One skilled in the art would be able to form the claimed devices based on these bonding techniques without any undue experimentation” and as such, it is believed that the claims 54 –60, 62 overcome the written description rejection under U.S.C. 112, first paragraph. Such is not persuasive.

At the outset, the examiner strenuously disagrees with the Applicants’ position that the skilled artisan would be able to manufacture the claimed devices based on these bonding techniques without any undue experimentation. Paragraph [0069] refers to techniques that generate shapes of constructs and not bonding of two layers. Moreover, Paragraph [0069] states that “then heating the structure as described in U.S. Patent No 3,562,820”. Patent 3,562,820 discloses at col. 2, lines 24-35, at col. 3 lines 11-20, col. 4, lines 71-73, bonding techniques comprising swelling of the exposed surfaces so as to produce an adhesive or glue like used as bonding agent to generate a multi-layered structure. Clearly, the disclosure does not provide sufficient guidance commensurate with the scope of the claims. As discussed above, and for the reasons of record, the disclosure provided by the applicant is not fully enabled for the scope embraced by the claims because applicant does not provide sufficient guidance to make and use a variety of bonding techniques as embraced and set forth by the invention in light of the

guidance provided in the specification and knowledge available to one of ordinary skill in the art in relation to a genus of unspecified bonding techniques as claimed.

Claim Rejections - 35 USC § 103

Claims 36-45, 53, and 63-65 remain rejected under 35 USC § 103 as being unpatentable over Voytik-Harbin et al., et al., et al., (US Patent No. 6,444,229) in view of Stinson et al., (US 2004/0111149 A1).

Reply to applicant arguments as they relate to rejection of Claims 36-44, 53, and 63-65 under - 35 USC § 103.

On page 8 of Remarks, Applicants argue that Voytik-Harbin et al. do not teach a gelatin suspension as claimed. Applicants contend that the present application teaches that an injectable material "can be readily made by comminuting the invention 5 into small fibrils, fragments, or the like, then suspending them in solution, such as, but not limited to, a biocompatible gelatin suspension. See paragraph [0089]. This is in no way the same as the gel taught by Voytik-Harbin et al: Indeed, Voytik-Harbin et al. teach the formation of a gel by digesting a submucosal tissue and raising the pH by the addition of a buffer that does not leave a toxic residue, and has a physiological ion concentration and the capacity to hold physiological pH". Such is not persuasive.

As an initial matter, Applicants argue limitations that are not present in the claims; the claims are not limited to any process of preparation of the injectable, viscous gelatin suspension. Hence the argument is not persuasive. Additionally, Voytik-Harbin et al., clearly teaches providing an

injectable, viscous gelatin suspension as required by independent claim 36 in the following paragraphs: "the shape retaining gels of the present invention are translucent, having an optical density ranging from about 0.1 to about 2.0 at A405 nm" (col. 8, lines 41-45). See also column 10, lines 1-22, for teachings of the injectable therapeutic composition wherein "the injected material then gels at the in vivo site of injection thus immobilizing the composition at the injection site" (col. 10, lines 12-13).

Claims 45-53 and 63-65 remain rejected 35 USC § 103 as being unpatentable over any of Kropp (Urology, 1995), Whitson (US patent No. 5,997,575) and Bonadio (US patent No. 5,942,496) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

Reply to applicant arguments as they relate to rejection of Claims 45-53 and 63-65 under - 35 USC § 103.

On page 9 of Remarks, Applicants argue that none of the cited references teaches a bioabsorbable collagenous biomaterial formed into the shape of a coil as required by independent claim 45. Additionally, Applicants contend that a coil finds particular advantages not recognized by the design shapes taught by the cited references such as "a braided coil structure can be unwound or crumpled to facilitate delivery via a catheter. Once at the desired site of implantation, the coil can form back into its coiled shape. See, for example, the present application at paragraph [0091]". Moreover, applicants states that the "Examiner indicates that Whitson teaches flat plates but they can also include other shapes such as screens, opposed cylinders or rollers and complementary nonplanar surfaces" (col. 6, lines 5-10) or hollow sphere

or pouch (col. 7, line 22)". However, Applicants argue that "this reference, as well as any of the other cited references, in no way teaches or suggests the formation of a coiled structure. A coil will generally be formed in an entirely different manner than the shapes taught by the cited references. For example, a coil can be formed as a braided or non-braided structure. In either case, the material can be wound around a mandrel to form a coil". Such is not persuasive.

As an initial matter, Applicants argue limitations that are not present in the claims; hence the argument is not persuasive. The examiner notes that Applicants teach contemplated structural limitation of a coil structure wherein the coil structure can be formed as a braided or non-braided structure (paragraph [0091]). Therefore the "shape of a coil" as claimed can be broadly interpreted as any rigid or flexible material, which can be fashioned into a spiral or helical shape. In contrast to Applicants' argument, the claimed coiled shape 13 is merely one of the embodiments of the instant inventions wherein strips 13 of the biomaterial 10 can be shaped into a braid 24, as seen in the exemplary FIG. 5, to increase its strength or size (paragraph [0091]). However, this limitation is not present in the claims. Thus, as stated in the previous office action, it would have been obvious for one of ordinary skill in the art as a matter of design of choice to construct the collagenous biomaterial in any shape known in the prior art including the claimed coiled structure of independent claim 45, so long as the shape of the biocompatible material is compatible with an instrument used in the medical art of grafting for assisting with the placement of the biomaterial within the body of a grafted subject, particularly since shaping or molding techniques including sutures, staples, biocompatible adhesives are well-known in the prior art of record.

Claims 45-53 remain rejected and new claims 63-65 are rejected under 35 USC § 103 as being unpatentable over any of Badylak et al., (WO 96/24661), Badylak 2 (WO 96/25179), Cook et al., (WO 98/22158), Fearnot (US 6,358,284), Badylak 3 (US 2004/0078076) each of them take with Stinson et al., (US 2004/0111149 A1) for the reason explained above and of record.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- First paragraph- New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 54 recites the limitations “wherein said strips are bonded to one another by using sutures, staples, or biocompatible adhesives or by dehydrating overlapping strips”. The as-filed specification teaches that “Shapes can be made by using sutures, staples, biocompatible adhesives such as collagen binding pastes, or dehydrating overlapping structures then heating the structure as described in U.S. Pat. No. 3,562,820” (p. 10, line 2). The disclosed teachings refer to

“shape the construct” and not to fuse or bind a plurality of tela submucosa. Thus is not clear that the Applicant was in possession of a genus of undefined of strips bonded to one another “by using sutures, staples, or biocompatible adhesives or by dehydrating overlapping strips” at the time the application was filed.

Conclusion

Applicant response filed on 09-19-2007 has been considered by the Examiner but is moot in view of the new grounds of the rejection, which is necessitated by the claims amendment.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding his application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any

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inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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